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10/553,671

10/17/2005

Valerie Bicard-Benhamou

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1527

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7590

02/13/2009

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.

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ARLINGTON, VA 22201

EXAMINER

BLAKELY III, NELSON CLARENCE

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/553,671

**Applicant(s)**

BICARD-BENHAMOU ET AL.

**Examiner**

NELSON C. BLAKELY III

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 33-44 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 7, 21, 23-28, 34, 35 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/10/2008.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application Status***

Claims 1-44 of the instant application are pending. Claims 29-32 are withdrawn, and claims 33-44 are added pursuant to Applicant's Amendment, filed 11/10/2008. Accordingly, instant claims 1-28 and 33-44 are presented for examination on their merits.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, a formulation for topical applications, in the reply filed on 03/05/2008, and Applicant's arguments, filed 11/10/2008, are acknowledged. The traversal is on the ground(s) that unity of invention for the combination of an independent claim to a product, a process specially adapted for manufacturing the product, and the use of the product does not require a technical feature that defines a contribution over the prior art. Applicant's traversal has been carefully considered in its entirety, but is not found to be persuasive. The requirement of unity of invention, referred to in Rule 13.1, shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical features" shall mean those technical features that define a contribution when each of the claimed inventions, considered as a whole, makes over the prior art.

Accordingly, by the reasons mentioned *supra*, and those made of record at pages 2-8 and pages 2 and 3 of the previous Office Actions, mailed 02/14/2008 and

05/13/2008, respectively, the requirement is still deemed proper, and the finality is maintained.

### ***Applicant's Amendment***

Applicant's Amendment, filed 11/10/2008, wherein the specification and claims 5-7, 9, 17, 20-22 and 33 are amended, and claims 34-44 are added, is acknowledged and has been fully considered.

### ***Information Disclosure Statement***

The Information Disclosure Statement, filed 11/10/2008, is acknowledged and considered to the extent that each reference is a proper citation on a US patent.

The Information Disclosure Statement, filed 10/17/2005, wherein cited reference nos. 008-010 were lined through, previously failed to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Accordingly, cited reference no. 008 was supplied by the Examiner in the first Office Action, mailed 05/13/2008, and cited reference nos. 009 and 010 were supplied by Applicant with the IDS, filed 11/10/2008. Additionally, cited reference nos. 004 through 007, which were prematurely accepted whereby Applicant did not provide a legible copy, are being supplied by the Examiner with the instant Office Action.

***Objections***

***Specification (Withdrawn)***

The previous objections are hereby withdrawn pursuant to Applicant's Amendment, filed 11/10/2008.

***Specification (New)***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The disclosure is objected to for the following informalities:

The use of the trademark IRIODIN®, for example, has been noted in this application on page 8, lines 6-9. A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that trademarks are also listed on page 9, line 15, for example.

On page 16, lines 16-22, the recitations of bacteria should be italicized, i.e., *Staphylococci*.

On page 23, lines 11-16, for example, the antibiotics mentioned are not trademarks or proper nouns, thus, Applicant is encouraged to use lowercase formatting, i.e., vancomycin.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

### ***Claims (Withdrawn)***

The previous objections are hereby **withdrawn** pursuant to Applicant's Amendment, filed 11/10/2008.

### ***Claim Objections***

Claims 1-28 and 33-44 are objected to for the following informalities:

With regard to claims 1 and 2, although both forms of the recitations "side-effects" (claim 1, line 3) and "side effects" (claim 2, line 2) are conventionally accepted, Applicant is encouraged to be consistent with regard to the precision and accuracy of the claim language.

With regard to claims 1 and 44, Applicant is encouraged to use the recitation "obtained" in lieu of "obtainable".

With regard to claims 2-28 and 33-43, Applicant is encouraged to use the recitation "The" in lieu of "A" at the beginning of the dependent claims, i.e., "A formulation according to claim 1,...".

With regard to claims 2, 7 and 28, Applicant is encouraged to use the conventional U.S. spelling of the recitations "malodour", "coloured" and "photostabiliser", respectively, i.e., "malodor", "colored" and "photostabilizer".

With regard to claim 21, the antibiotics listed are not proper nouns; therefore, Applicant is encouraged to use the lowercase formatting, i.e., vancomycin.

With regard to claims 23-28, Applicant is encouraged to use the recitation "comprises" in lieu of "comprise" for the precision and accuracy of the claim language.

With regard to claim 34, although both recitations "20 and 45 °C" and "20 °C and 45 °C" are correct, Applicant is encouraged to be consistent with regard to the precision and accuracy of the claim language. See claim 1, wherein the unit follows each degree recitation.

With regard to claim 35, the recitation "up" is not needed. Applicant is encouraged to remove said recitation for the precision and accuracy of the claim language. See claims 36 and 37.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 (Withdrawn)***

The previous rejections are hereby withdrawn pursuant to Applicant's Amendment, filed 11/10/2008.

***Claim Rejections - 35 USC § 103 (Withdrawn)***

The previous rejections are hereby withdrawn pursuant to Applicant's Amendment, filed 11/10/2008.

***Response to Arguments***

Applicant's arguments, with respect to claims 38-40, have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112 (New Grounds of Rejection)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38-40 recite the limitation "antimicrobial compound" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claims 38-40 depend, does not recite the limitation "antimicrobial



compound". For purposes of examination, the Examiner has interpreted the antimicrobial compound to be silver oxide.

### ***Response to Arguments***

Applicant's arguments, with respect to claims 1-28 and 33-44, have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103 (New Grounds of Rejection)***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-19, 24 and 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo *et al.* (U.S. Patent No. 6,030,627; Cited by Applicant), in view of Abe *et al.* (U.S. Patent No. 4,375,373) and Bagala, Sr. (U.S. Patent 7,045,007B2), as evidenced by Iler (U.S. Patent No. 2,885,366) and Galinsky *et al.* ["Basic

Pharmacokinetics and Pharmacodynamics." in: Remington: The Science and Practice of Pharmacy (Baltimore, Lippincott Williams & Wilkins, 2006), p. 1171].

With regard to instant claims 1-3, 6-19, 24 and 33-44, Seo *et al.* disclose, in reference claims 1, 3, 4, 7 and 8, an antimicrobial cosmetic pigment comprising inorganic cosmetic pigment, amorphous glassy coating layer of metal oxide having a lattice structure formed over the surface of said inorganic cosmetic pigment and antimicrobial metals or antimicrobial metal ions intercalated inside the lattice structure of said coating layer of metal oxides. In the instant excerpt, Seo *et al.* further disclose wherein the inorganic cosmetic pigment may be mica, zinc oxide, and titanium dioxide, for example, and wherein the coating layer of metal oxide comprises silica alone, or as the main ingredient and one or more of zinc oxide and ferric oxide, for example. Furthermore, in the instant excerpt, Seo *et al.* disclose wherein the antimicrobial metal is one or more of silver and zinc, for example, and comprises 0.00001 to 5.0 parts by weight to 100 parts of the coating layer of metal oxide. Seo *et al.* disclose, in column 1, lines 17-23, and column 2, lines 9-18, wherein adding preservatives to cosmetics prevents deterioration, change of smells, i.e., malodour, and change of fragrance by microbes, or microorganisms, and germination of fungi by sterilizing or restraining the breeding of the microbes. In column 5, lines 33-45, Seo *et al.* disclose wherein the composition of the coating layer of the metal oxides is generally similar to glass, and as a means of preventing the decrease of its function as a cosmetic pigment because of the transparency due to its lower refraction index, a small quantity of ferric oxide, for example, is added, for coloring purposes, as an inorganic coloring agent. Seo *et al.*

disclose, in column 8, lines 34-58, that the cosmetic of the reference invention may be in the form of a cream, wherein the antimicrobial cosmetic pigments, which encompass inorganic cosmetic pigments, amorphous glassy coating layer of metal oxide, and antimicrobial metals, for example, may be in a quantity for use in cosmetics of 0.001-50.0 weight percent.

Seo *et al.* fail to disclose specifically wherein said pigment particles with silver oxide are prepared by agitating a suspension at a temperature between 10 °C and 60 °C for 4 to 24 hours; however, Abe *et al.* disclose, in the Abstract, a stable inorganic pigment having the surface thereof a continuous coating of fine amorphous silica. Additionally, Abe *et al.* disclose, in column 1, lines 19-21, wherein the pigments of the reference invention may be used in cosmetics, for example. In column 4, lines 15-42, Abe *et al.* disclose where any type of metal powder pigment, i.e., silver and zinc, may be used in the reference invention. Furthermore, in the instant excerpt, Abe *et al.* disclose wherein the inorganic pigment may comprise titanium dioxide and zinc oxide, for example. Abe *et al.* disclose, in column 6, lines 22-49, wherein a uniform slurry, or thick suspension, comprising the pigments, is heated at about 60 °C to 250 °C for preferably from 1 to 5 hours. In the instant excerpt, Abe *et al.* disclose where mechanical shearing and ultrasonic waves may advantageously be used to redisperse secondary particles of pigment. Abe *et al.* disclose, in column 11, lines 7-24, where the metal powder pigment is preferably coated in an amount of about 3 to 15 weight percent. Abe *et al.* fail to disclose specifically wherein the slurry, or thick suspension, is heated at a temperature between 20 °C and 45 °C, and wherein the slurry is agitated, or

mixed, from 8 to 20 hours. Additionally, though Seo *et al.* disclose, in column 5, lines 33-45, wherein the composition of the coating layer of the metal oxides comprises a small quantity of ferric oxide, for example, for coloring purposes, as an inorganic coloring agent, Seo *et al.* and Abe *et al.* fail to disclose specifically wherein the L, a and b values are  $-6 \leq \Delta L \leq 6$ ,  $-5 \leq \Delta a \leq 5$ , and  $-5 \leq \Delta b \leq 5$ , respectively. However, it is not inventive to discover the optimum ranges or regimens by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and MPEP §2144.05(II). In addition, Galinsky *et al.* recite in the left column of page 1171, lines 12-27 of text, that it is recognized that drug therapy may be optimized by designing regimens that account for the concentration of a drug, for example, to achieve a desired pharmacological response. Therefore, the determination of the optimum characterization of the formulation and optimum ranges would have been a matter well within the purview of one of ordinary skill in the art, at the time of the invention, through no more than routine experimentation. A skilled artisan would have envisaged the antimicrobial cosmetic pigment comprising inorganic pigment, amorphous glassy coating layer of metal oxide, i.e., silica, and antimicrobial metals, i.e., silver, as disclosed by Seo *et al.*, prepared by mixing, or agitating, a slurry, or suspension, at a temperature of 60 °C for about 5 hours, as disclosed by Abe *et al.* One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a heat, chemical, and light resistant, stable antimicrobial inorganic pigment. It would have been obvious to one of ordinary

skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Seo *et al.* fail to disclose specifically wherein the inorganic pigment is an effect pigment, wherein the mica is a synthetic mica, or wherein one or more layers of transparent, semitransparent or opaque, selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, i.e., titanium dioxide, are arranged as alternating layers wherein the refractive index  $n > 1.8$  and  $n < 1.8$ . However, Bagala, Sr. discloses, in reference claims 1-8, an effect pigment comprising metal oxide-coated laminar platelets in which the platelets are a mixture of about 5 to 90% platy glass and 90 to 5% mica, and in which the effect pigment exhibits visual homogeneity. In the instant excerpt, Bagala, Sr. further discloses wherein the metal oxide comprises iron and/or titanium oxides, and wherein the metal oxide coating comprises a plurality of layers. Additionally, in column 1, lines 44-58, Bagala, Sr. discloses that the addition of coatings to a platelet so that the luster, color, and color homogeneity are maintained is a very complex process, and originally, the only platy substrate which achieved any significant use in commerce was mica. Furthermore, in the instant excerpt, Bagala, Sr. discloses that historically, the largest class of effect pigments based on thin film interference were those based on a mica substrate, and it became evident that other substrates, such as synthetic mica, could be used since it contributes certain effect attributes, due to variations in transparency, refractive index, bulk color, thickness and surface and edge features, for example.

Therefore, a skilled artisan would have envisaged modifying the antimicrobial cosmetic pigment comprising inorganic pigment, amorphous glassy coating layer of metal oxide, i.e., silica, and antimicrobial metals, i.e., silver, as disclosed by Seo *et al.*, prepared by mixing, or agitating, a slurry, or suspension, at a temperature of 60 °C for about 5 hours, as disclosed by Abe *et al.*, such that the "effect pigment", or inorganic pigment, comprises metal oxide-coated laminar platelets, i.e. synthetic mica, as disclosed by Bagala, Sr. One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a visually homogeneous blend of coated effect pigments with antimicrobial activity. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Seo *et al.* fail to disclose specifically wherein the inorganic pigment particles are platelet-shaped, spherical, or needle-shaped, or wherein the outer coating comprising silica is a "protective coating layer"; however, Iler discloses in column 1, lines 15-42, wherein the products of the reference invention ordinarily assume the form of finely divided spheres, plates, or fibers, i.e. needle-shaped, of a solid material other than silica enveloped with a skin of impenetrable amorphous silica. Additionally, in column 3, lines 1-17, Iler discloses wherein the substrates, comprising metal oxides, i.e., titanium dioxide and zinc oxide are typical of cores, whereas plate-like mineral silicates include various varieties of mica, for example. Therefore, a skilled artisan would have envisaged the antimicrobial effect pigments of the combined teachings Seo *et al.*, Abe *et al.* and Bagala, Sr. to conform to a spherical or platelet-like shape, as evidenced by

ller. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 1-3, 6-19, 24 and 33-44, is *prima facie* obvious over the combination of the aforementioned teachings.

Claims 4, 5 and 20-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo *et al.* (U.S. Patent No. 6,030,627; Cited by Applicant), in view of Abe *et al.* (U.S. Patent No. 4,375,373) and Bagala, Sr. (U.S. Patent 7,045,007B2), as evidenced by Iler (U.S. Patent No. 2,885,366) and Galinsky *et al.* ["Basic Pharmacokinetics and Pharmacodynamics." in: Remington: The Science and Practice of Pharmacy (Baltimore, Lippincott Williams & Wilkins, 2006), p. 1171.], as applied to claims 1-3, 6-19, 24 and 33-44 above, and further in view of Vollhardt (U.S. Patent No. 6,274,124B1) and Scott *et al.* (U.S. Patent No. 6,482,397B1), as evidenced by Hashim (Oil Palm Bulletin, Vol. 47, pages 37-48; 2003) and De Tommaso (International Publication No. WO02/04012A1).

The teachings of Seo *et al.* are recited *supra*.

With regard to instant claims 4, 5, and 20-28, Seo *et al.* disclose, in column 1, line 66, through column 2, line 8, that in cosmetics, many kinds of raw materials are used permitting microbes, or microorganisms, to reproduce making use of the carbon source in them. Seo *et al.* fail to disclose specifically wherein a protein is a suitable

substrate for microorganisms, or wherein antioxidants and customary excipients, such as waxes and paraffins, are included in the formulation. However, in the Abstract and Table 1, Hashim discloses, for evidentiary purposes, that cosmetic products contain variable amounts of nutrients that support microbial growth. In the instant excerpt, Hashim further discloses conventional raw materials used in cosmetic products, such as waxes, paraffins, protein, colour and pigments, preservatives and antioxidants.

Seo *et al.* fail to disclose specifically the inclusion of ingredients, such as one or more UV filters, skin-protecting or skin-care active ingredients, or at least one photostabilizer. However, Vollhardt discloses, in the Abstract, a conventional cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin of humans. Vollhardt discloses, in column 4, line 36 through column 5, line 54, wherein the formulation is suitable for the addition of 1,2-pentanediol, an emulsifier, which in addition to UV filter substances, may comprise antioxidants and inorganic pigments. Furthermore, in the instant excerpt, Vollhardt discloses wherein the formulation may further comprise at least one antiperspirant and/or at least one skin whitening compound, which would reasonably be construed by a skilled artisan, at the time of the invention, to be skin-protecting or skin-care active ingredients. In column 1, lines 42-49, Vollhardt discloses the UV filter substance 2-phenylbenzimidazol, a known photostabilizer. Additionally, in column 2, lines 12-20, Vollhardt discloses wherein the aforementioned inorganic pigments, coated or uncoated, are known to be used in sunscreen products to help protect the skin from UV rays. In the instant excerpt, Vollhardt further discloses wherein the inorganic pigments,



such as oxides of titanium, zinc and iron, are typically used in addition to organic UV filter substances. Therefore, a skilled artisan would have envisaged the modified antimicrobial cosmetic pigment of the combined teachings, as disclosed by Seo *et al.*, Abe *et al.* and Bagala, Sr., further comprising conventional active ingredients, such as UV filter substances, skin-protecting or skin-care active ingredients, and at least one photostabilizer, as disclosed by Vollhardt. One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a novel cosmetic or dermatological composition with increased water resistance and light (sun) protection. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Seo *et al.* and Vollhardt fail to disclose specifically the inclusion of ingredients, such as at least one antibiotic, at least one self-tanning agent and vitamins; however, Scott *et al.* disclose, in reference claims 1-3, a composition comprising an artificial tanning effective amount of a self-tanning agent, i.e. dihydroxyacetone (DHA), a coloring agent, and a cosmetically acceptable carrier adapted for topical application to human skin. Additionally, Scott *et al.* disclose, in column 1, lines 52-65, that though DHA is used as a widely accepted self-tanning agent, coloring agents are included in sunless tanning compositions to provide the applier the ability to more accurately assess where they have applied the compositions to their skin. In column 4, line 49, through column 5, line 42, Scott *et al.* disclose wherein the composition further comprises antimicrobial agents, or antibiotics, preservatives, antioxidants, vitamins and

waxes, for example. In the instant excerpt, Scott *et al.* further disclose wherein antimicrobial agents and preservatives inhibit microbial growth in the compositions, and can be used to treat infected, or potentially infected, areas of skin. Scott *et al.* and Seo *et al.* fail to disclose specifically wherein the antibiotic is vancomycin; however, De Tommaso discloses, on page 1, lines 1-7, an anhydrous pharmaceutical composition comprising vancomycin, a glycopeptide antibiotic having a broad spectrum of antimicrobial activity, for topical use. Therefore, a skilled artisan would have envisaged the modified antimicrobial cosmetic pigment of the combined teachings, as disclosed by Seo *et al.*, Abe *et al.*, Bagala, Sr. and Vollhardt, further comprising conventional active ingredients, such as at least one antibiotic, i.e., vancomycin, at least one self-tanning agent, i.e., dihydroxyacetone, and vitamins, as disclosed by Scott *et al.*, and evidenced by De Tommaso. One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking a composition comprising a light, water, and heat resistant antimicrobial inorganic pigment to be applied topically, wherein the included coloring agent aides in assuring even application of said composition. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

Accordingly, the instant invention, as claimed in claims 4, 5 and 20-28, is *prima facie* obvious over the combination of the aforementioned teachings.

***Double Patenting (Maintained and Amended)***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 6-13, 18, 34 and 38-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7 and 14-16 of copending application no. 10/553,668 (Serial No. '668), in view of Park *et al.* (U.S. Patent No. 6,372,236B1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. application no. '668 claims an antimicrobial pigment, obtainable by agitating at 20-45 °C, a suspension comprising one or more inorganic pigments, i.e., synthetic mica, and silver oxide, and/or glass substrates with an outer layer of TiO<sub>2</sub>, for example, wherein the one or more inorganic pigments are in each

case, platelet-shaped, spherical or needle-shaped. Furthermore, U.S. application no. '668 claims wherein the substrates are coated with one or more layers of transparent, semitransparent or opaque, selectively absorbing, nonselectively absorbing or nonabsorbing metal oxides, such as  $\text{TiO}_2$ , arranged as alternating layers with a refractive index  $n > 1.8$  and  $n \leq 1.8$ , which may additionally contain organic and/or inorganic colorants or elements as dopant. U.S. application no. '668 additionally claims wherein the values for L, a, and b for the inorganic pigments and antimicrobial pigments are  $-6 \leq \Delta L \leq 6$ ,  $-5 \leq \Delta a \leq 5$ , and  $-5 \leq \Delta b \leq 5$ , respectively. U.S. application no. '668 claims wherein the silver oxide is substituted by zinc oxide, and wherein the antimicrobial compound is in the range of 0.001 to 10% by weight, based on the inorganic pigment.

U.S. application no. '668 does not claim specifically wherein the antimicrobial pigment is formulated into a cream; however, Park *et al.* discloses, in reference claim 1, a composition for skin care consisting essentially of ceramides, cholesterol, fatty acids, phospholipids, and phytosphingosine, for example, present in the composition in respective amounts effective to form the composition as a stable emulsion (i.e., cream) and to provide the composition with antimicrobial activity.

Therefore, a skilled artisan would have envisaged the antimicrobial pigment, comprising one or more inorganic pigments, i.e., synthetic mica, and silver oxide, as disclosed by application no. '668, formulated into an emulsion, i.e., cream, as disclosed by Park *et al.* One of ordinary skill in the art would have been motivated to combine the teachings of the aforementioned references when seeking to elicit the antimicrobial effects of the antimicrobial pigment through conventional applications, such as topical

administration via a cream. It would have been obvious to one of ordinary skill in the art, at the time of the invention, because the combined teachings of the prior art are fairly suggestive of the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's Amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NELSON C. BLAKELY III whose telephone number is

(571) 270-3290. The examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614  
February 1, 2009

/N. C. B. III/  
Examiner, Art Unit 1614